PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	20.10.2004
Applicant's or agent's file reference JNR/PG4881	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/07937	17.07.2003	19.07.2002

Applicant
GLAXO GROUP LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the International preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	de Santiago Gomez, A Tel. +49 89 2399-8224

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/PG4881	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/07937	International filing date *(day/month/year)* 17.07.2003	Priority date *(day/month/year)* 19.07.2002
International Patent Classification (IPC) or both national classification and IPC B65D83/04		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.01.2004	20.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Bevilacqua, V Telephone No. +49 89 2399-7983

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/07937

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-49 as originally filed

Claims, Numbers

1-25 as originally filed

Drawings, Sheets

1/11-11/11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-15 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,4,7,8,15
	No:	Claims	1,2,5,6,9-12,14
Inventive step (IS)	Yes:	Claims	
	No:	Claims	3,4,7,8,15
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations

see separate sheet

This object is achieved by means of the features common to both the independent claims 1 and 16, namely:

- a medicament dispenser for use with a medicament carrier having multiple distinct medicament doses carried thereby, said dispenser having an internal mechanism for dispensing the distinct medicament doses carried by said medicament carrier, said mechanism comprising:

a) receiving means for receiving the medicament carrier

b) release means for releasing a distinct medicament dose from the medicament carrier on receipt thereof by said receiving means

c) an outlet, positioned to be in communication with he medicament dose releasable by said release means

d) indexing means for individually indexing the distinct medicament doses of the medicament carrier and

e) counting means for counting eah time a distinct medicament dose of the medicament carrier is indexed by said indexing means

The documents D1 and D2 disclose both such a device comprising all features common to independent claims 1 and 16 (see in particular D1 page 99 (vue arrière) and D2 paragraph 51).

The subject-matter of claim 1 (first invention) differs from the known device in that the counting means is provided as a distinct electronic counter unit that is reversibly receivable by the medicament dispenser.

The effect of this feature is apparently that the counter can display information in a digital form and is readily re-usable .

The subject-matter of claim 16 (second invention) differs from the known device in that manipulating means to manipulate an analogue count indicium provided by the analogue counting means are provided.

The effect of this feature is apparently that the analogue count indicium provided by the

Re Item IV
Lack of unity of invention

The international preliminary examining authority is of the opinion that the application does not comply with the requirements of unity of invention as set forth in the PCT regulations (Article 34(3), Rule 68(1) PCT).

1. Reference is made to the following documents:

   D1: Annales Francaises De Chronometrie Et De Microtechnique, Observatoire De Besancon. Besancon, Fr (1998), 47, 97-105

   D2: US 2002/066451 A1 (DAVIES MICHAEL BIRSHA ET AL) 6 June 2002 (2002-06-06)

2. The separate inventions are:

   a) A medicament dispenser for use with a medicament carrier having multiple distinct medicament doses carried thereby, comprising:

indexing means and counting means for counting eah time a distinct medicament dose of the medicament carrier is indexed by said indexing means

wherein said counting means is provided as a distinct eletronic counter unit that is reversibly receivable by the medicament dispenser according to any of claims 1 to 15.

   b) A medicament dispenser for use with a medicament carrier having multiple distinct medicament doses carried thereby, comprising indexing means and

analogue counting means for counting eah time a distinct medicament dose of the medicament carrier is indexed by said indexing means and manipulating means to manipulate an analogue count indicium provided by said analogue counting means according to any of claims 6 to 8.

The present application relates to the general problem of counting the doses of medicament dosed from a dispenser.

analogue counting means gives an understandable indication to the user.

Thus, the special technical features (analysed above) of each invention are clearly not the same. Furthermore, they are not "corresponding", since, as can be seen from the analysis, they have neither same or corresponding effects, nor are they relating to the same objective. A further consideration under Rule 13.2 PCT revealed no further features derivable from the application that may be considered as constituting contributions over the art common to all inventions. Hence, the inventions do not meet the circumstances of Rule 13.2 PCT and Rule 13.1 PCT is not satisfied.

For the purposes of Article 34(3)(c) PCT and in accordance with Rule 68.5 PCT claims 1-15 are considered to relate to the main invention.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. State of the art

Reference is made to the following documents:

D3: US-B-6 360 739 (GODFREY JAMES WILLIAM ET AL) 26 March 2002 (2002-03-26)

D4: US-A-5 544 647 (EBELING FREDERICK A ET AL) 13 August 1996 (1996-08-13)

D5: US-A-6 029 659 (O'CONNOR JAMES A) 29 February 2000 (2000-02-29)

1. Novelty

The document D3 is regarded as being the closest prior art to the subject-matter of independent claim 1, and discloses (the references in parentheses applying to this document see figures 1 and 7):

a medicament dispenser for use with a medicament carrier (2) having multiple distinct medicament doses carried thereby, said dispenser having an internal mechanism (1,20,40,41) for dispensing the distinct medicament doses carried by said medicament carrier, said mechanism comprising:

a) receiving means (41) for receiving the medicament carrier

b) release means (6,4,see figure 1) for releasing a distinct medicament dose from the medicament carrier on receipt thereof by said receiving means
c) an outlet (5), positioned to be in communication with he medicament dose releasable by said release means
d) indexing means (44,45) for individually indexing the distinct medicament doses of the medicament carrier and
e) counting means (47) for counting eah time a distinct medicament dose of the medicament carrier is indexed by said indexing means

wherein said counting means (47) is provided as a distinct eletronic counter unit (see column 7 lines 15-20) that is reversibly receivable (see column 5 lines 9-19) by the medicament dispenser.

The subject-matter of independent claim 1 is therefore not novel (Article 33(2) PCT).
The applicant should note that the expression "multiple distinct medicament doses" contained in claim 1 has been interpreted as multiple doses of medicament distinct in the dosed state, the applicant is therefore invited to clarify this expression.
Also the expression indexing means is very broad and therefore D3 is considered to disclose said feature.

Dependent claims 2,5,and 6,9-12 and 14 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, see for example D3 figure 7 and column 7 line 20 where:
-the dispenser has an housing and said electronic counter unit is reveribly receivable in said housing (claim 2)
-the electronic counter unit comprises a unit housing, a LCD display and a protecting viewing window (claim 5)

2.Inventive step

Dependent claims 3,4,7,8 and 15 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D3-D5 and the corresponding passages cited in the search report.